

## **REMARKS**

### **Formal Matters**

Claims 34-36 are pending in the application. No claim is amended.

### **Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 34-36 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being ambiguous with respect to the terms "ErbB4," "ErbB3," and "ErbB2." Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

Applicants claim a method of detecting the presence of ErbB4 in a sample using a polypeptide that binds to ErbB4 receptor but not ErbB2 receptor or ErbB3 receptor under experimentally comparable conditions. In contrast to the Examiner's suggestion, the terms for the receptors, "ErbB4," "ErbB3," and "ErbB2," are not ambiguous because not only Applicants' disclosure, but also the relevant literature, describe these known receptors such that one of ordinary skill in the art would understand the metes and bounds of Applicants' invention. The ErbB receptor family is described throughout the instant specification, such as at, for example, page 1, line 19 to page 2, line 18; at page 21, lines 3-12; in art cited by Applicants in the specification at page 5, lines 11-14 (Plowman et al., Nature, 1993, and Sliwkowski, M et al. J. Biol. Chem. (1994), both of record); and page 81, line 23 to page 85, line 15 (Example 4B-D). Specifically, the Plowman and Sliwkowski references disclose subcloning and separate expression of the receptors using cDNA of the *erbB2*, *erbB3*, and *erbB4* genes. Thus, the terms for the ErbB family of receptors as well as the receptors themselves are well known and understood in the art. Based on Applicants' disclosure coupled with the relevant literature, one of ordinary skill in such an ordinarily skilled artisan to recognize the metes and bounds of the claimed invention.

Having overcome the rejection, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

Rejection Under 35 U.S.C. § 102(b) (Goodearl et al. (US5,530,109))

Claims 34-36 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Goodearl et al. (US5, 530,109, the “109” patent). Applicants respectfully traverse the rejection as applied and as it might be applied to the currently pending claims for the reasons provided below.

Applicants claim a method of detecting ErbB4 receptor in a sample comprising contacting the receptor with a polypeptide comprising an EGF-like domain, the EGF-like domain comprising an amino acid sequence having at least 75% amino acid sequence identity to SEQ ID NO:4 of Applicants' specification. The Examiner suggests at page 2 of the Office Action that the binding of GGF with a receptor as described at columns 9 and 13 of the '109 patent anticipates Applicants' claims. Such is not the case. First, there is no suggestion in the '109 patent of binding of a polypeptide to ErbB4 receptor. Second, because Applicants showed, above, that the ErbB2, 3, and 4 receptors are distinguishable, it cannot properly be said that mention of the binding of a polypeptide to ErbB2 in the '109 patent in any way anticipates a method of binding a polypeptide to ErbB4 in Applicants' claims. This is particularly true where, according to Applicants' claims, such polypeptide does not bind to ErbB2 under similar experimental conditions. Third, the deduced amino acid sequence of nucleic acid SEQ ID NO:155 of the '109 patent does not appear to have 74% amino acid sequence identity to Applicants' SEQ ID NO:4 as the Examiner suggests. In fact, it appears to have far less sequence identity. This issue is moot, in any event, because Applicants' claim a method using a polypeptide that has at least 75% amino acid sequence identity to SEQ ID NO:4. Thus, the '109 patent in no way provides each and every element of Applicants' claims and, thus, cannot be considered to anticipate Applicants' claims. For this reason, Applicants respectfully submit that the rejection should be withdrawn and the claims allowed.

### SUMMARY

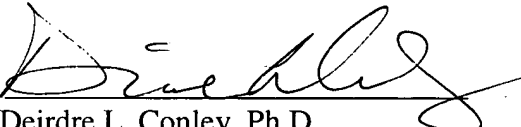
Claims 34-36 are pending in the application. The rejections under Section 112, second paragraph and under Section 102(b) have been overcome. Withdrawal of the rejections and allowance of the claims is respectfully requested.

If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This response/amendment is submitted with a transmittal letter and petition for a three-month extension of time and fees. In the unlikely event that this document is separated from the transmittal letter or if fees are required, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Respectfully submitted,  
GENENTECH, INC.

Date: December 23, 2003

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Clean Set of All Pending Claims

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34. A method of detecting ErbB4 receptor in a sample, the method comprising:
- a) contacting a detectably labeled polypeptide with the sample, wherein the polypeptide comprises an EGF-like domain, the EGF-like domain comprising an amino acid sequence having at least 75% amino acid sequence identity to SEQ ID NO:4, and wherein the polypeptide binds to ErbB4 receptor but not ErbB2 receptor or ErbB3 receptor under experimentally comparable conditions; and
  - b) detecting binding of the polypeptide to a protein in the sample.
35. The method of claim 34 wherein the sample comprises a cell expressing ErbB4 receptor on its surface.
36. The method of claim 35 wherein the sample is a mammalian tissue sample.